

## REMARKS

### I. Introduction

Following entry of the present amendment, claims 25 – 37 canceled, and claims 38 – 43 are presented. Support for the new claims may be found throughout the specification as originally filed, e.g., page 7, line 15 – page 8, line 4, page 12, lines 2 – 8, and originally filed claims 11 and 18 (now canceled). It is believed no new matter has been added.

### II. 35 USC § 112, first paragraph rejection

Claims 25 – 37 are rejected under 35 USC 112, first paragraph, because the specification, while enabled for a method of incidence risk reduction of non-cancerous symptoms or pathologies associated with androgen signaling of polycystic ovary syndrome by administering lycopene, the specification does not enable any person in the art in preparing a method of incidence risk reduction of any and/or all non-cancerous symptoms or pathologies associated with androgen comprising administering an effective amount of lycopene. Additionally, the Examiner finds the specification is not enabling for a method of prophylactic nutritional supplementation of healthy subjects to reduce the risk reduction of non-cancerous symptoms or pathologies with androgen comprising administering an effective amount of lycopene.

Applicants respectfully traverse the rejection, but have presented new claims directed to incidence risk reduction of polycystic ovary symptom associated with androgen signaling in order to advance prosecution, and request the rejection be withdrawn.

### III. 35 USC § 103(a) rejection

Claims 25 – 37 are rejected under 35 USC 103(a) as being unpatentable over Lorant et al. (US 6,623,769) in view of Murad (US 5,962,517) and de Salvert (US 5,827,520). Lorant in view of de Salvert (US 5,827,520). The Examiner finds Lorant et al. teaches an effective amount of lycopene is administered to treat pathologies associated with androgen signaling such as acne, and would also inherently have the same underlining functional effect as the claimed invention. The Examiner finds that Lorant teaches an effective amount of lycopene is administered to a subject in need thereof to treat pathologies associated with androgen signaling, but does not teach the combination of lycopene and vitamins E and C administered to a subject in need

thercof to treat pathologies associated with androgen signaling. However, the Examiner finds Murad teaches vitamin E treats pathologies associated with androgen signaling, and de Salvert teaches vitamin C treats pathologies associated with androgen signaling. Thus, according to the Examiner, it would have been obvious to one of skill in the art to modify the teachings of Lorant to include vitamin E and C as taught by Murad and de Salvert.

Applicants respectfully traverse the rejection, however, have amended the claims such that the androgen signaling related symptom is polycystic ovary syndrome. It is submitted none of the references, either alone or in combination, teach or suggest the use of lycopene for such a condition.

Lorant et al. utilizes lycopene in a mixture to have anti-collagenase activity. Lycopene is also taught to be useful in treatment of scalp/acne and use as an agent for combating free radicals. However, Lorant et al. is silent as to the activity of lycopene in polycystic ovary syndrome.

Murad also deals with acne, and discloses a vitamin E source in combination with a host of other ingredients. Similar to Lorant et al., Murad is also silent on the use of vitamin E in risk reduction of polycystic ovary syndrome.

de Salvert fails to remedy the deficiencies of Lorant et al and Murad. Salvert is a topical composition containing, for example, vitamin C, in a particular vehicle which is transparent or translucent, homogenous and stable (in the absence of a surfactant and/or stabilizer). Salvert fails to teach or suggest risk reduction of polycystic ovary symptom associated with androgen signaling.

As the references fail to teach or suggest all of the limitations of the claims, Applicants request the rejection be withdrawn.

## V. Summary

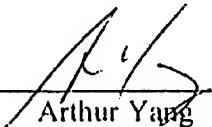
Applicants have made a *bona fide* attempt to address all matters raised by the Examiner. Applicants respectfully submit that the application is now in condition for allowance, and therefore respectfully request that the outstanding rejections be withdrawn and that a Notice of Allowance be issued. If any remaining matters need to be resolved, Applicants respectfully request an interview with the Examiner prior to any official action being taken by the Office in

response to these arguments and amendments in order to facilitate allowance of the pending claims.

It is believed no other fees are presently required. If a fee is required, please charge the same to Deposit Account 50-4255.

Respectfully submitted,

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